

CLAIMS

What is claimed is:

1. An implantable source of therapeutic radiation consisting of:
 - a. A sealed, biocompatible capsule made of plastic that is transparent to therapeutic radiation, containing;
 - b. The source of therapeutic radiation consisting of a radioactive isotope substantially uniformly mixed in a fluid carrier that is resistant to radiation polymerization in its fluid phase, but can be induced to solidify by raising its temperature.
 - c. A marker visible by fluoroscope or x-ray film or ultrasound imaging or nuclear magnetic resonance imaging (MRI);
 - d. A radioactive isotope selected from the group: Pd-103, I-125, Cs-131.
2. The implantable source of Claim 1 in which the capsule is made of mechanically strong, biocompatible, plastic material such as high density polyethylene or PEEK.
3. The implantable source of Claim 1 wherein the capsule is made from medical grade PEEK.
4. The implantable source of Claim 1 having a socket or universal joint, or other connecting configuration as an integral part of the capsule, such that it accommodates attaching spacers and makes possible linear strands and planar arrays.
5. A functional unit with 2, 3, 4 or 6 connecting ends which, with capsules of Claim 4, make possible linear strands of sources and spacers, and planar arrays of triangular, square, and hexagonal patterns of sources and spacers.
6. A functional unit of Claim 5 wherein it controllably releases medicines of several types, including anti-inflammatory drugs, local anesthetics, antibiotics, anti-cancer adjuvants or radiation enhancing drugs.
7. A functional unit comprising material that absorbs radio waves to produce heat, making possible an effective means of adding hyperthermia to the radiation treatment of the target organ.
8. A spacer or other attachment to a connection joint on the implantable source of Claim 1 that has expandable petals or barbs which hinder the motion through tissue of the attachment and its attached seeds.
9. A functional unit, attached to a capsule of Claim 1 by the socket or universal joint, consisting of a malleable plug forming a seal, if required, or a simple retaining element depending on interference with the interior wall on the needle, so that the seed train will only leave the

needle as a result of the force applied by the therapist during the implant procedure. The plug can be made with plastic foam such that it is readily imaged with ultrasound so the physician can easily detect the first seed leaving the needle.

10. A plastic carrier of the radioisotope of Claim 1b consisting of an epoxy based fluid that is substantially uniformly mixed with the radioisotope to form a fluid that can be jetted through an ink-jet head into the plastic capsule, or into a separate mold, where curing is initiated by heating and it is cured in place in the capsule, or in a separate mold.

11. The plastic carrier of Claim 10 where the carrier is the formulation:

(percentages are weight percent):

- (1)Radioactive residue 17%
- (2)Triethyleneglycoldivinylether 55%
- (3) epoxy resin 18%
- (4)Borontrifluoride monoethylamine 2%
- (5)Propylene carbonate 8%

To perform the manufacturing method disclosed herein, the radioactive residue is dissolved in components (2) and (3), while component (4) is dissolved in a portion of the solvent (5). All of the liquids are then combined to form the source material. The source material is then jetted in the proper quantity into the volume of the seed shell that it is to occupy, and the source material is then heated to approximately 190°C, to initiate curing.

12. A seed with a plastic carrier consisting of the radioisotope co-mingled with enough non-radioactive isotope such that the resulting carrier is visible with fluoroscope or x-ray film negating the need for a separate marker, but which remains sufficiently transparent to the curative radiation to be a practical therapeutic device.

13. The transmission of therapeutic radiation through the source of Claim 12 is between 20% and 80%.

14. The radioisotope of Claims 12 and 13 is Pd-103, produced by neutron activation in a nuclear reactor and the remaining stable Pd isotopes, augmented by addition of high specific activity Pd-103 or non-radioactive palladium to adjust the transmission of the carrier.

15. The radioisotope of Claims 12 and 13 is I-125, augmented by addition of non-radioactive iodine, or other chemically compatible heavy element, to adjust the transmission of the carrier.

16. An implantable source of therapeutic radiation comprising:

- e. A sealed, biocompatible capsule made of plastic that is transparent to therapeutic radiation, containing;
 - f. The source of therapeutic radiation consisting of a radioactive isotope substantially uniformly mixed in a fluid carrier that is resistant to radiation polymerization in its fluid phase, but can be induced to solidify by raising its temperature.
 - g. A marker visible by fluoroscope or x-ray film or ultrasound imaging or nuclear magnetic resonance imaging (MRI);
 - h. A radioactive isotope selected from the group: Pd-103, I-125, Cs-131.
17. The implantable source of Claim 1 in which the capsule is made of mechanically strong, biocompatible, plastic material such as high density polyethylene or PEEK.
18. The implantable source of Claim 1 in which the capsule is made from medical grade PEEK.
19. The implantable source of Claim 1 which has a socket or universal joint, or other connecting configuration as an integral part of the capsule, such that it accommodates attaching spacers and makes possible linear strands and planar arrays.
20. Biodegradable spacers with 2, 3, 4 or 6 connecting ends which, with capsules of Claim 4, make possible linear strands of sources and spacers, and planar arrays of triangular, square, and hexagonal patterns of sources and spacers.
21. The spacers of Claim 5 that are designed to controllably release medicines of several types, including anti-inflammatory drugs, local anesthetics, antibiotics, anti-cancer adjuvants or radiation enhancing drugs.
22. The spacers of Claim 5 that contain material that absorbs radio waves to produce heat, making possible an effective means of adding hyperthermia to the radiation treatment of the target organ.
23. A spacer or other attachment to a connection joint on the implantable source of Claim 1 that has expandable petals or barbs which hinder the motion through tissue of the attachment and its attached seeds.
24. A functional unit, attached to a capsule of Claim 1 by the socket or universal joint, consisting of a malleable plug forming a seal, if required, or a simple retaining element depending on interference with the interior wall on the needle, so that the seed train will only leave the needle as a result of the force applied by the therapist during the implant procedure. The plug can be made with plastic foam such that it is readily imaged with ultrasound so the physician can easily detect the first seed leaving the needle.

25. A plastic carrier of the radioisotope of Claim 1b consisting of an epoxy based fluid that is substantially uniformly mixed with the radioisotope to form a fluid that can be jetted through an ink-jet head into the plastic capsule, or into a separate mold, where curing is initiated by heating and it is cured in place in the capsule, or in a separate mold.

26. The plastic carrier of Claim 10 where the carrier is the formulation:

(percentages are weight percent):

- (1)Radioactive residue 17%
- (2)Triethyleneglycoldivinylether 55%
- (3) Cycloaliphatic epoxide resin 18%
- (4)Borontrifluoride monoethylamine 2%
- (5)Propylene carbonate 8%

To perform the manufacturing method disclosed herein, the radioactive residue is dissolved in components (2) and (3), while component (4) is dissolved in a portion of the solvent (5). All of the liquids are then combined to form the source material. The source material is then jetted in the proper quantity into the volume of the seed shell that it is to occupy, and the source material is then heated to approximately 190°C, to initiate curing.

27. A seed with a plastic carrier consisting of the radioisotope co-mingled with enough non-radioactive isotope such that the resulting carrier is visible with fluoroscope or x-ray film negating the need for a separate marker, but which remains sufficiently transparent to the curative radiation to be a practical therapeutic device.

28. The transmission of therapeutic radiation through the source of Claim 12 is between 20% and 80%.

29. The device of claim 1 wherein the radioisotope is Pd-103, produced by neutron activation in a nuclear reactor and the remaining stable Pd isotopes, augmented by addition of high specific activity Pd-103 or non-radioactive palladium to adjust the transmission of the carrier.

30. The device of claim 1 wherein the radioisotope is I-125, augmented by addition of non-radioactive iodine, or other chemically compatible heavy element, to adjust the transmission of the carrier.

31. A brachytherapy device for use in radiation treatment of an affected tissue region, the brachytherapy device comprising:

a sealed hollow outside cylindrical capsule consisting of a biocompatible nonabsorbable polymeric matrix surrounding an inside cylindrical solid radioactive seed composed of a radioactive isotope uniformly mixed with and disbursed throughout a biocompatible nonabsorbable polymeric matrix.

32. A brachytherapy device of Claim 31 wherein the radioactive isotope is comprised of a powder selected from the group consisting of Pd-103, I-125 or CS-131.

33. A brachytherapy device of Claim 31 wherein the biocompatible nonabsorbable polymeric matrix is selected from the group consisting of high density polyethylene, high density polyaryletheretherketone or medical grade polyaryletheretherketone.

34. A brachytherapy device of Claim 31 further comprising a radiographically detectible element for locating the brachytherapy device within the body of a patient.

35. A brachytherapy device of Claim 31 further comprising a concave socket joint configuration disposed at either end of the external surface of the outside capsule so as to accommodate at either end, a biodegradable spacing connector comprised of one or more ball joint elements.

36. A brachytherapy device of Claim 35 wherein the biodegradable spacing connector is selected from the group of said connectors comprised of one ball joint element, two ball joint elements, three ball joint elements, four ball joint elements or six ball joint elements.

37. A method of making a radioactive seed of the brachytherapy device of Claim 31, comprising the steps of:

- (a) mixing a radioactive isotope dispersed in a solvent, with a biocompatible nonabsorbable polymeric matrix to form a fluid homogenous mixture;
- (b) injecting said fluid homogenous radioactive mixture through an ink-jet head into a cylindrical mold;
- (c) heating the mold to cure the fluid homogenous radioactive mixture into a solid radioactive cylindrical form;

(d) removing the cured solid radioactive cylindrical form from the mold.

38. The process according to Claim 37, wherein the cured solid radioactive cylindrical form is encased within a thin layer of biocompatible nonabsorbable polymeric matrix to seal.

39. The process according to Claim 38, wherein a radiographically detectible element is inserted for locating the brachytherapy device within the body of a patient before the mold is heated to cure the fluid homogenous radioactive mixture into a solid radioactive cylindrical form.

40. The process according to Claim 38, wherein the radioactive isotope is comprised of a powder selected from the group consisting of Pd-103, I-125 or CS-131.

41. The process according to Claim 38 wherein the biocompatible nonabsorbable polymeric matrix is selected from the group consisting of high density polyethylene, high density polyaryletheretherketone or medical grade polyaryletheretherketone.